

FBI Laboratory Practices for Internal Audits

1 Purpose

Internal audits verify that operations conform to the requirements of the FBI Laboratory quality system. They also provide management with information regarding the quality system. These practices also satisfy the requirements of the FBI Laboratory Quality Assurance Manual and the applicable accrediting body(ies).

2 Scope

These practices apply to the Quality Manager, Quality Assurance (QA) Specialists, and/or other FBI Laboratory personnel who conduct, facilitate, and/or acknowledge Forensic Analysis Support Unit (FASU) directed internal audits in the FBI Laboratory.

3 Practices

3.1 Auditor Training

An auditor must successfully complete an approved training course. The Quality Manager will determine if a training course will be approved and the Audit Program Manager will maintain a list of approved training courses. The Audit Program Manager will also maintain a list of auditors who have successfully completed an approved course.

3.2 Long-Term Audit Planning

Activities performed by FBI Laboratory personnel will be audited annually. The Audit Program Manager will prepare a schedule for audits annually based on an evaluation of laboratory activities, as changes in those activities, and the results of previous audits. A summary of this risk evaluation will be recorded, approved by the Quality Manager and maintained. The schedule will identify the topics and approximate dates of the audits. This schedule is a guide and may be changed at the discretion of the Quality Manager or Audit Program Manager.

3.3 Scheduling the Audits

Throughout the year, the Audit Program Manager will ensure the QA representatives of the units to be audited are contacted to determine mutually agreeable dates for the audits.

3.4 Preparing for the Audit

3.4.1 The Audit Program Manager will identify an audit team leader(s) when appropriate,

and ensure auditors are identified, as needed, to assist in performing an audit. The Audit Program Manager will ensure the selected auditors are on the list of internal auditors. If an audit team leader is identified, the audit team leader will coordinate the audit, as directed by the Audit Program Manager.

3.4.2 The Audit Program Manager will ensure an audit checklist is prepared and provided to the auditee(s) and the auditor(s). The audit checklist should be organized in such a way as to prompt the auditor(s) to review records, interview personnel, and/or observe conditions and facilities when necessary. The auditor(s) may be provided with additional materials so they can prepare for the audit.

3.4.3 The Audit Program Manager or audit team leader will meet with the audit team(s), when necessary, to provide instruction and guidance prior to conducting the audit.

3.5 Conducting the Audit

3.5.1 Pre-audit Communication

The Audit Program Manager or audit team leader will communicate the scope of the audit and address any questions and/or concerns with the auditee.

3.5.2 Auditing

The auditor(s) will, as necessary, review records, interview personnel, and/or observe conditions and facilities to collect data on conformance with requirements and effectiveness of quality control measures. For appropriate topics, the auditor(s) will directly observe a sampling of examinations within each discipline and/or category of testing. The audit checklist will be used to record the audit data and any pertinent questions, observations, and/or comments identified during the audit.

3.5.3 Post-audit Communication

The Audit Program Manager will inform the unit QA representative, the Unit Chief(s), and the Technical Leader(s) of the preliminary audit data in writing. This communication will include the completed audit checklist. The Audit Program Manager or audit team leader may prepare a summary checklist to consolidate multiple audit checklists. This communication should occur as soon as possible following the audit. The auditee should inform the Audit Program Manager and if applicable, the audit team leader, of any disagreements with the preliminary audit data. These issues will be considered by the Audit Program Manager and, if possible, resolved before the audit report is written.

3.5.3.1 The preliminary audit data will be prepared by the Audit Program Manager when an audit is conducted on a FASU Program.

3.6 Reporting the Audit

3.6.1 The Audit Program Manager will provide an audit report to each unit(s) for every audit topic conducted to formally notify the Unit Chief(s) and the Technical Leader(s) of their audit results. An audit report will record any proficiencies, potential nonconformities, potential undesirable situations, and/or nonconformities.

3.6.2 The audit report will be issued by the Audit Program Manager. When a *Corrective Action Request* (7-254) will be issued, the audit report will be reviewed and approved by the Quality Manager. The issuance and approval will be recorded on the audit report by their respective signatures and dates.

3.6.2.1 An audit report will be prepared by the Audit Program Manager when an audit is conducted on a FASU Program. The appropriate Section Chief will approve the audit report.

3.6.3 The Audit Program Manager will issue the audit report to the Unit Chief(s) and the Technical Leader(s). If a concession or correction was identified to address a nonconformity, the audit report will identify those actions. If an audit report contains a corrective action(s) or a preventive action(s), each *Corrective Action Request* (7-254) and *Preventive Action Request* (7-261) will be referenced in the audit report. Any *Corrective Action Request* will be generated according to the Laboratory Operations Manual (LOM) - Practices for Addressing a Nonconformity. Any *Preventive Action Request* will be generated according to the LOM - Practices for Preventive Action.

3.6.3.1 When an audit is conducted on a FASU Program, the audit report will be issued to the Quality Manager.

3.7 Responding to an Audit Report

The Unit Chief(s) and Technical Leader(s), or when applicable, Quality Manager, will acknowledge receipt of the audit report by signing and dating the report and returning the original report to the Audit Program Manager.

3.8 Closing Out the Audit

3.8.1 Preventive and Corrective Actions

When a *Preventive Action Request(s)* and/or *Corrective Action Request(s)* associated with an audit is closed out, the audit for that unit can be closed.

3.8.2 Audit Closure Notification

The unit QA representative, Unit Chief(s), and Technical Leader(s), or when applicable, Quality Manager, will receive an audit closure notification from the Audit Program Manager in writing to inform them that the audit is closed. An audit is considered closed when the Unit Chief(s) and

Technical Leader(s), or when applicable, Quality Manager have acknowledged receipt of the audit report, all concessions and corrections have been recorded, and all *Preventive Action Request(s)* and/or *Corrective Action Request(s)* have been closed out.

4 Records

The following records will be generated and/or retained through one accreditation cycle as a result of these practices:

- Annual audit schedule and associated risk evaluation summary.
- Completed audit checklists and if generated, a summary checklist.
- Audit reports and any associated responses will be retained permanently.
- Any associated *Preventive Action Request(s)* and/or *Corrective Action Request(s)*
- Preliminary audit data.
- Audit closure notifications.
- List of approved auditor training courses.
- List of approved auditors.

5 References

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

FBI Laboratory Operations Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17020 – Conformity Assessment – Requirements for the Operation of Various Types of Bodies Performing Inspections, International Organization for Standardization, Geneva, Switzerland, 2012.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

| Rev. # | Issue Date | History |
|--------|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10 | 06/03/19 | Added section 3.1 describing training requirements for auditors. Generalized requirement in section 3.3 as other QA personnel may schedule an audit. In sections 3.5.3.1 added requirement regarding when audits are conducted on a QA program. Removed redundant requirement for sending a copy of PAR or CAR from section 3.8.1. Updated section 3.8.2 as Audit Program Manager will send all audit closure notifications. Updated Records section to add lists of approve auditor training courses and approved auditors. Updated list of references in section 5. |
| 11 | 12/21/20 | Grammatical and editing changes made throughout for clarity Removed: References to TEDAC QA Program Manager or TEDAC QA Program throughout 2 – Added: facilitate, and/or acknowledge; Replaced: quality assurance with internal 3.2 – Section reworded for risk evaluation 3.6.2 – Added: When a <i>Corrective Action Request</i> (7-254) will be issued, the audit report will be reviewed and approved by the Quality Manager 4 – Added: risk evaluation with audit schedule and any associated <i>Preventive Action Request(s)</i> and/or <i>Corrective Action Request(s)</i> 5 – Added: LOM and ISO/IEC 17020 |

Approval

Redacted - Signatures on File

Laboratory Director

Date: 12/18/2020

Quality Manager

Date: 12/18/2020